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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,410	12/12/2000	Burkhard Goke	0206-UTL-9	8826

7590 10/27/2006

ARNOLD & PORTER
Attn: IP Docketing Departement, Room 1126B
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Washington, DC 20004-1206

EXAMINER	
MOHAMED, ABDEL A	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 10/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/719,410	GOKE ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *44-46 and 48-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *44-46 and 48-54* is/are allowed.

6)☒ Claim(s) *55-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

ACKNOWLEDGMENT TO AMENDMENT, REMARKS AND STATUS OF THE CLAIMS

1. The amendment and remarks filed 09/05/06 are acknowledged, entered and considered. In view of Applicant's request claims 55-58 have been amended. Claims 44-46 and 48-58 are now pending in the application. The rejection under 35 U.S.C. 102(b) over the prior art of record is maintained for the reasons set forth in the previous Office action.

CLAIMS REJECTION-35 U.S.C. § 102(b)

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 55-58 remain rejected under 35 U.S.C. 102(b) as being anticipated by Schirra et al (J. Clin. Invest. Vol. 101, No. 7, pp. 1421-1430, 1998).

Applicant's arguments filed 09/05/06 have been fully considered but they are not persuasive. Applicant's arguments that claims 55-58 have been amended to specify "an exendin or exendin agonist analog". The Schirra reference teaches that exendin (9-39) amide (an exendin analog) is a specific and competitive **antagonist** of GLP-1. The Schirra reference fails to teach or suggest the use of an exendin or an exendin agonist

analog to reduce the risk of a cardiovascular or cerebrovascular event of claims 55-58. Thus, the Schirra reference fails to teach or suggest every element of the claimed invention is unpersuasive. Contrary to Applicant's arguments claims 55-58 as currently amended read on alternative language (i.e., … an exendin **or exendin agonist analog**….). Thus, the claims as amended are broadly directed to a method for reducing a risk of cardiovascular event or a method for reducing a risk of cerebrovascular event by administering a composition comprising an exendin **or an exendin agonist analog**, wherein said composition contains an amount of the exendin **or exendin agonist analog** effective to enhance the regularity of insulin responses, or the amplitude thereof, in reaction to changes in plasma glucose, thereby reducing the risk of a cardiovascular event or reducing the risk of a cerebrovascular event, respectively (i.e., directed to different population than the allowed claims 44-46 and 48-54). The prior art of Schirra et al discloses the administration of exendin, i.e., without the alternate language of "**or exendin agonist analog**" (as currently amended) to reduce the risk of a cardiovascular or cerebrovascular event for the reasons of record, in the absence of evidence to the contrary the exendin and its use thereof as disclosed by the prior art anticipate claims 55-5-8 as drafted.

NEW GROUND OF REJECTION

The following is a new ground of rejection necessitated by Applicant's amendment.

CLAIMS REJECTION-35 U.S.C. 112, 1st PARAGRAPH

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 55-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no description in the instant specification for a method for reducing a risk of cardiovascular event or a method for reducing a risk of cerebrovascular event by administering a composition comprising an exendin **or an exendin agonist analog**, wherein said composition contains an amount of the exendin **or exendin agonist analog** effective to enhance the regularity of insulin responses, or the amplitude thereof, in reaction to changes in plasma glucose, thereby reducing the risk of a cardiovascular event or reducing the risk of a cerebrovascular event, respectively in the manner claimed in claims 55-58. It is noted as stated by Applicant on the remarks filed 09/05/06 that for "**an exendin agonist analog**" can be found on page 6, line 29 through page 7, line 2; page 7, lines 15-26; and page 8, lines 7-12 of the specification. However, none of the cited pages above in the instant specification support methods involving exendin or an exendin agonist analog thereof (i.e., administering to an individual exendin or an exendin agonist analog thereof) for

methods for reducing a risk of cardiovascular or cerebrovascular events in the manner claimed in claims 55-58. Pages 6, line 29 through page 7, line 2 discloses a receptor-binding compound which further comprises a polynucleotide or an agent which activates the release of GLP-1, a molecule which activates the GLP-1 receptor, or a GLP-1 receptor binding compound comprising a chemically constructed molecule, peptide analogs, or agonists of GLP-1. On page 7, lines 15-26, the instant specification discloses a GLP-1 which includes GLP-1 mimetics comprising glucagons-like peptides and related peptides and analogs of GLP-1 that bind to GLP-1 receptor protein such as the GLP-1 (7-36) amide receptor protein. Further, on page 8, lines 7-12 the instant specification discloses GLP-1 mimetics that also are agonists of β-cells include, for example, chemical compounds specifically designed to activate GLP-1 receptor. GLP-1 antagonists include exendin (9-39) amine, an exendin analog, which is a potent antagonist of GLP-1 receptors. Thus, in view of various peptide analogs or agonists of GLP-1, in view of GLP-1 mimetics that bind GLP-1 receptor protein such as GLP-1 (7-36) and in view of GLP-1 mimetics that also are agonists of β-cells, which include, for example, chemical compounds specifically designed to activate GLP-1 receptor. GLP-1 antagonists include exendin (9-39) amine, an exendin analog, which is a potent antagonist of GLP-1 receptors, the scope of the currently presented claims 55-58 is not supported in the instant specification.

ACTION IS FINAL, NECESSITATED BY AMENDMENT

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

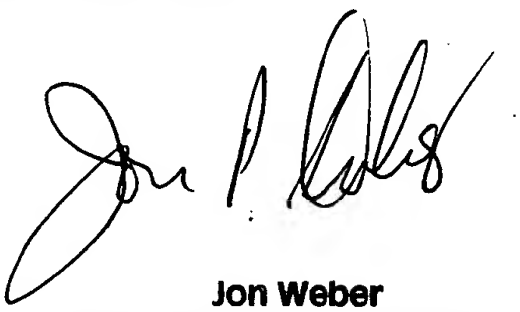
CONCLUSION AND FUTURE CORRESPONDANCE

5. Claims 44-46 and 48-54 are allowed and claims 55-58 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (571) 272 0955. The examiner can normally be reached on First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tsang Cecilia can be reached on (571) 272 0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Jon Weber
Supervisory Patent Examiner

AAM Mohamed/AAM
October 18, 2006